IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYVLANIA

Civil Action No. 2:14-cv-00824 MSG

DEFENDANTS' BRIEF PURSUANT TO COURT ORDER DATED JULY 14, 2021

I. Defendants' Production

Caremark's production of documents and data to Relator in this matter has been extensive and costly. It has lasted almost a full year, during which Caremark has produced more than 1.8 million pages of documents.¹ Caremark has also produced more than two billion data records relating to claims and Prescription Drug Events ("PDE"). The cost to Caremark of collecting and producing these materials to Relator already well exceeds \$1 million and counting.

Caremark primarily has collected documents for production from the archived e-mails of an agreed set of custodians. The archived e-mail includes all e-mail and e-mail attachments that were sent or received by the custodians during the agreed time frame (2010-2016), regardless of whether a custodian subsequently saved, deleted, or moved a particular e-mail. After months of negotiating sets of custodians and search terms to be applied to the custodial e-mail collected by Caremark, the parties agreed on twenty-two search strings in March 2021.

Based on Caremark's investigation, it determined that most responsive documents would likely be contained in custodial e-mail, with the exception of (1) discrete categories of documents such as Generic Effective Rate ("GER") reconciliations that were collected and maintained in central repositories on share drives and (2) claims data and PDE data, which were housed in databases. Caremark produced thousands of documents collected from centralized repositories maintained on share drives, as well as metadata reflecting the file paths of the share drives from which the files were collected.

¹ By comparison, Caremark produced approximately 189,855 documents to the government during its investigation of Relator's claims (those documents were reproduced to Relator in 2019). As a result of document discovery in this matter, Relator has already obtained from Caremark approximately *ten times as many documents* as did the government. And that does not even include productions by Aetna and SilverScript in response to Relator's Rule 45 subpoenas, which together total more than 200,000 pages of additional documents.

II. CMS Communications

Caremark has already taken reasonable steps to search for and produce documents reflecting communications with CMS. Indeed, one of the search terms the parties negotiated (Search Term #6) was specifically designed to capture such material.² Caremark has produced over 7,000 documents as a result of applying Search Term #6. Relator's complaint that "relatively few" documents have been produced concerning communications to and from CMS is thus simply inaccurate.

The reasonableness of Caremark's search for CMS communications is validated not only by the quantity of documents already produced, but also by their contents. The produced documents include, for example, communications with CMS employees such as Cheri Rice, Director of Medicare Plan Payment Group, regarding subject matter directly related this litigation. *See* CVS-Behnke-1129308. The produced documents also include, for example, guidance transmitted by CMS relating to DIR reporting and PDE submissions. See CVS-Behnke-0319255-68; CVS-Behnke-0248415-41. And Relator supports her argument that there are "less formal communications between CMS and industry participants" by citing multiple examples of such documents <u>already produced</u> by Caremark in this litigation. Br. at 1.

Relator's chief complaint appears to be that Caremark has not gone even further to search for yet more documents. But Relator offers no concrete proposal for what further searches should be conducted. Instead, Relator vaguely asserts that Caremark should produce documents "regardless of whether they happen to reside in individual email files." Br. at 2. Relator's

² Search Term #6 included the term "hhs.gov," which captures documents reflecting e-mails to or from (or even just containing) CMS e-mail addresses, and other agreed subject matter terms. The full search string as agreed by the parties was: (("Part D" or Medicare or MEDD) AND ("negotiated price" or "actual cost" OR (GER or (generic w/3 effective*))) AND (PDE OR "Prescription Drug Event" OR "DIR" OR (direct w/3 indirect) OR (price w/3 report*)) AND "hhs.gov")).

contention that Caremark has "refused to identify" share drives or repositories, *id.*, misses the point. Caremark's investigation to date has not uncovered any share drive or similar source that served as a centralized location for CMS communications during the relevant time period.³

Notwithstanding Relator's failure to proffer any concrete proposals of her own, Caremark has told Relator's counsel that it is attempting to determine whether there are further options to locate additional CMS communications (if such documents exist). Caremark expects to propose to Relator any such further sources or searches by August 11, 2021.

III. Reconciliation Files, Price Submissions to CMS, and Contracts

Caremark has completed a reasonable search for responsive reconciliation files and contracts. At Relator's request, Caremark undertook additional investigation to evaluate whether any known responsive documents were missing. As a result of those efforts, Caremark identified a small volume of additional responsive documents and has produced those to Relator. As for "price submissions to CMS," Relator does not explain what she means. And she ignores that Caremark has produced more than two billion data records reflecting, *inter alia*, "price" information associated with Medicare Part D claims for Aetna and SilverScript. In any event, Relator does not contend that Caremark has actually failed to produce documents in any of these categories; by her own admission, she does "not know if there will be issues in terms of missing contracts or spreadsheets." Br. at 3.

Relator's sole complaint under this heading in her brief is that certain spreadsheets produced by Caremark supposedly are "incomplete" because they were produced exactly as they

³ Relator assumes that "searching department share drives" might be necessary if "employees who were likely to have communicated with CMS did not permanently maintain complete e-mail files." Br. at 2. That concern is premised on a fundamental misunderstanding of Caremark's method for collecting e-mail. Caremark collected e-mail from a repository that archived all e-mail sent or received by custodians, regardless of what individuals did with it thereafter.

were stored in the normal course of business, without what Relator calls "embedded" files.

Relator's criticism is misplaced. To the extent responsive spreadsheets included actual "embedded" files, Caremark did produce them. When a file is "embedded" in a spreadsheet, the two files are packaged together such that the "embedded" file actually becomes part of the spreadsheet file. Relator's complaint instead concerns what are properly referred to as "linked" files, where a spreadsheet contains only a reference to the "linked" file, and the "linked" file exists and is stored completely separate from the spreadsheet file.

The difference is important. The ESI Protocol ordered by the Court explicitly requires parties to produce "embedded" files and details how such files should be produced. ECF No. 100, ¶ 2.3, 3.6, 3.8. By contrast, the ESI Protocol contains *nothing* requiring a party to identify, track down, collect, or produce "linked" documents. This is not an inadvertent omission. Production of "embedded" files is feasible precisely because they are joined together with the associated spreadsheets and thus are automatically captured by the collection process along with the spreadsheets in which they are embedded. By contrast, there is no known (let alone reasonable) systematic method for automatically collecting (or even identifying) "linked" documents, and Relator certainly has not identified any such method. Each "linked" document must be individually identified through manual review, as Relator implicitly acknowledges in her brief. Br. at 3 (Relator has "identified a limited sample, to date" but "we and our experts may identify additional documents as our review continues"). Even as to particular linked files Relator might manually identify, Caremark then would have to undertake a document-bydocument search for each individual linked file. Neither the ESI Protocol in this case nor the Federal Rules imposes on Caremark any obligation to undertake such a burdensome and timeconsuming task, and Relator has not (and cannot) explain why it would be proportionate to impose such a burden on Caremark here.

IV. Commercial Claims Data

Relator has alleged violations of the False Claims Act concerning Medicare Part D prescription drugs, and Caremark has already produced more than two billion PDE and claims records associated with *Medicare Part D* transactions—which are distinct from commercial transactions—for Aetna and SSIC beneficiaries. Relator contends that Caremark should produce similar data regarding commercial claims, despite having asserted no cause of action regarding those claims. It is unclear how much of a burden this would represent, given that Relator never actually explains what she deems "appropriate commercial claims data or payment information." Br. at 4. Indeed, even Relator appears to be unsure what she wants; her request for relief is only that the Court "direct Caremark to engage in good faith negotiations as to a production of commercial claims data (we would discuss production of a sample)." *Id.* Relator has yet to make any clear proposal on this subject (with or without sampling). Relator also has yet to explain why production of data for individual commercial transactions is necessary when Caremark has already produced reconciliations addressing commercial transactions in aggregate.

V. Index to IA Share File

Relator makes an extraordinary request that Caremark be ordered to produce "any index to the IA share file . . . that has been prepared, even if the index was prepared by or at the direction of counsel." Br. at 4-5. The only such "index" that could be said to exist, however, derives from the *exact same metadata* Caremark produced to Relator. Relator's discovery vendor should be in the same position as Caremark's to generate such an "index."

VI. CVS Pharmacy / Documents Prior to 2010

Caremark disputes various assertions by Relator in these sections of her brief, but, as Relator concedes there is no need "for Court intervention at this time," Br. at 5, Caremark will reserve its arguments on these issues for a future date, should a real controversy arise.

Respectfully submitted,

WILLIAMS & CONNOLLY LLP

/s Daniel M. Dockery

dpark@wc.com

Counsel for Defendants

Dated: July 26, 2021

CERTIFICATE OF SERVICE

I, Daniel M. Dockery, hereby certify that on July 26, 2021, I caused a true and correct

copy of the foregoing to be filed electronically with the Clerk of the Court using the ECF system,

which will render this document available for viewing and downloading via the ECF system and

accomplish service on all parties entitled to service by automatically sending a notice of

electronic case filing to their counsel of record who are registered as ECF filing users.

/s Daniel M. Dockery

Daniel M. Dockery

Dated: July 26, 2021